

## **REMARKS**

Claims 1, 3, 10, 12, 13, 15-24, 27, 28, 30, 31, 34-37, 40, 41, 43, and 45-49 are pending in the application. Claim 2, 4-9, 11, 14, 25, 26, 29, 32, 33, 38, 39, 42 and 44 were canceled previously. Claims 1, 15, 22, and 24 are the only independent claims.

Claims 22-24, 27, 28, 34-37, 40, 41, and 43 have been withdrawn from consideration owing to a restriction requirement. Accordingly, only claims 1, 3, 10, 12, 13, 15-21, 30, 31, and 45-49 are currently under examination.

### ***Claims Rejections - 35 U.S.C. §§ 102 and 103***

Claims 1-3, 10, 12, 13, 15-21, 30, 31, and 45-49 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,840,013 to Lee et al. ("Lee").

Claims 1, 3, 10, 12, 13, 15, 30, 31, and 45-49 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,616,603 to Fontana.

**The Invention** Applicant's invention is directed to a flexible endoscope that has open working channels provided along the outer surface of the endoscope insertion member. The endoscope insertion member, like virtually all conventional endoscopes has an integral or inseparable image guide and an illumination guide. Applicant's endoscope differs from convention endoscopes in that applicant's endoscope incorporates working channels that are not surrounded by the endoscope insertion member but instead have a longitudinal slot in the outer surface of the insertion member, facilitating cleaning of the working channels.

**Conventional Endoscopes: the Problem** Through a biopsy or working channel of conventional flexible endoscopes, a lot of bio-burden is passed in and out of the

patient. For example, colonic contents containing stool, secretions and blood are suctioned through the channel. Biopsy forceps, snares and other flexible endoscopic operative devices are passed in and out of the biopsy channel(s). Procedures are performed during which bleeding occurs, causing direct blood products such as HIV or hepatitis viruses and many pathogenic bacteria, ova and parasites to enter the biopsy channel(s). These pathogens as well as gastrointestinal secretions are notoriously sticky and very difficult to remove with the long brushes that currently used to clean the biopsy channels after a procedure and prior to sterilization. The brushes are passed up and down the 2-meter-long flexible channels during a lengthy cleaning protocol, exposing nurses to toxic cleaning materials. When the endoscope is finally placed in the sterilizer, viruses, parasites and bacteria that have remained in the biopsy channel(s) because of poor access to cleaning instruments are not killed. In turn, they cross infect the next patient when the same instrument is used on that patient for a procedure. Again, if the mucosa (lining of the intestine) is breached on this second patient, these pathogens are introduced directly into the blood stream.

**Cited Prior Art** US Patent No. 6,616,603 to Fontana, is directed to an anoscope. An anoscope does not include optical viewing components but instead removably receives an endoscope for viewing purposes.

US Patent No. 5,840,013 to Lee et al. is directed to an instrument deployment device utilizable in association with an endoscope. More particularly, the Lee reference discloses a slotted tubular introducer member through which an endoscope is inserted basically for endotracheal operations (such as intubation). The introducer member can be

provided with an array of optical fibers evidently for illumination purposes (e.g., Figures 11A-11G). The introducer member is not provided with an image conduit.

**Differences Between Invention and Prior Art** Applicant's invention is directed to an endoscope with open working channels. Neither of the cited references discloses or suggests an *endoscope* that is integrally provided with an open or slotted, longitudinal working channel. Neither the anoscope of Fontana nor the slotted tubular introducer member of Lee et al. is an endoscope. Rather the anoscope of Fontana and the slotted tubular introducer member of Lee et al. are ancillary members that are inserted first into patients and subsequently receive an endoscope. The endoscopes of the prior art of the Fontana and Lee references (see Lee Figure 5) do not have open working channels that are temporarily covered (during use in a patient) and subsequently uncovered for cleaning.

To forestall further misinterpretation of applicant's claims, independent claims 1 and 15 have been amended herein to recite that the endoscope insertion member has an image guide inseparably incorporated therein. Amended claims 1 and 15 clearly describe an endoscope not an endoscope assembly or some aggregation of elements that include an endoscope and other parts. The channels are in the endoscope shaft itself, not some other ancillary member that is utilizable in conjunction with an endoscope.

In contrast, the anoscope of Fontana and the slotted tubular introducer member of Lee et al. are not endoscopes – they do not inseparably contain image-transmitting components.

It is not apparent as to how either Fontana or Lee et al. would make it obvious to provide an endoscope with an open or slotted, longitudinal working channel.

The amendments to claims 1 and 15 are not new matter, inasmuch as one skilled in the art understands full well that conventional flexible endoscopes have inseparable image guides. That is what is conjured up immediately in the mind of the gastroenterologist reviewing the present application. The specification has been amended to include the new language from claims 1 and 15, for antecedent purposes.

### *Conclusion*

For the foregoing reasons, independent claims 1 and 15, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,  
COLEMAN SUDOL SAPONE, P.C.

By: 

R. Neil Sudol

Reg. No. 31,669

714 Colorado Avenue

Bridgeport, CT 06605-1601

(203) 366-3560

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